# Responder AED

*automated external defibrillator*

# Operation and Service Manual

**What is Covered?**

Cardiac Science, Inc. ("Cardiac Science") warrants to the original purchaser that its products will be free of any defect in material and workmanship according to the terms and conditions of this Limited Warranty ("Limited Warranty"). For purposes of this Limited Warranty, the original purchaser is deemed to be the original end user of the product purchased. This Limited Warranty is NONTRANSFERABLE and UNASSIGNABLE.

**For How Long?**

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- Any Cardiac Science product case is opened by unauthorized personnel or if a product is used for an unauthorized purpose;
- Any Cardiac Science product is used in conjunction with incompatible parts or accessories, including but not limited to batteries. Parts and accessories are not compatible if they are not Cardiac Science products or the functional equivalent.

**If The Warranty Period has Expired…**

If your Responder AED is not covered by our Limited Warranty, call us for advice as to whether we can repair your Cardiac Science product, and for other repair information, including charges. Charges for non-warranty repairs will be assessed and are your responsibility. Upon completion of the repair, the terms and conditions of this Limited Warranty shall apply to such repair or replacement product for a period of 90 days.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state and country to country.

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# CAUTION

Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

## IMPORTANT

Read this carefully. It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

**Manufactured for GE Medical Systems Information Technologies**
**by Cardiac Science, Inc.**
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## PATENTS

This device is covered by the following U.S. and foreign patents:
5,792,190, 5,999,493, 5,402,884, 5,579,919, 5,749,902, 5,645,571, 6,029,085, 5,984,102, 5,919,212, 5,891,172, 5,674,266, 5,700,281, 5,891,173, 5,968,080, 6,263,239, 5,797,969, D402,758, D405,754, 5,909,138, 6,173,203, 6,088,616, 5,897,576, 5,955,956, 6,083,246, 6,064,909, 6,038,473, 5,868,794, 6,115,638, 6,366,809, 5,474,574, 6,246,907, 6,289,243, 6,411,846, 6,480,734, EP00756878
Other U.S. and foreign patents pending.

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## LIMITED WARRANTY

The Responder AED Manual and any and all information contained herein do not constitute any warranty as to the Responder AED or any related products in any manner whatsoever. The “Limited Warranty” is shipped with the AED and serves as the sole and exclusive warranty provided by Cardiac Science regarding Responder AED products.

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There is no charge to the customer for a customer support call. Please have the serial and model numbers available when contacting Customer Service. (The serial and model numbers are located on the underside of the Responder AED.)

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## DEFIBRILLATOR TRACKING

Defibrillator manufacturers and distributors are required, under the Safe Medical Devices Act of 1990, to track the location of defibrillators they sell. Please notify GEMS IT Customer Service in the event that your defibrillator is sold, donated, lost, stolen, exported, destroyed or if it was not purchased directly from General Electric, or an authorized distributor.

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# SECTION 1 - SAFETY

# OVERVIEW

This section presents safety information to guard against injury to persons and damage to the Responder AED.


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|---|---|
| Safety Alert Definitions | 7 |
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# SAFETY ALERT DEFINITIONS

## BEFORE OPERATING THE RESPONDER AED

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Responder AED.

## SAFETY TERMS AND DEFINITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:

⚠ ***DANGER:*** This alert identifies hazards that will cause serious personal injury or death.

⚠ ***WARNING:*** This alert identifies hazards that may cause serious personal injury or death.

⚠ ***CAUTION:*** This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

## PRODUCT REFERENCES

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintance common to the Responder AED will be referred to as “AED.”

Features and specifications vary, so please read this manual carefully.

# SAFETY ALERT DESCRIPTIONS

The following is a list of Responder AED safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the AED.

***DANGER:*** Fire and Explosion Hazard
Exercise caution when operating the AED close to flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

***WARNING***: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation electrodes clear of other electrodes or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

***WARNING***: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

***WARNING***: Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

***WARNING:*** Battery is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

***WARNING:*** Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to GEMS IT authorized service personnel.

***CAUTION:*** Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self test determines environmental conditions outside of the AED's operating parameters for 5 consecutive days, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions on page 48.

***CAUTION:*** Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

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***CAUTION:*** Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

***CAUTION:*** Use only Approved Equipment
Using batteries, electrodes, cables, or optional equipment other than those approved by GE may cause the AED to function improperly during a rescue.

***CAUTION:*** Possible Improper AED Performance
Using electrodes that are damaged or expired may result in improper AED performance.

***CAUTION:*** Serial Communication Cable
The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "*Remove Cable to Continue Rescue*" will be heard until you remove the serial communication cable.

***CAUTION:*** Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

***CAUTION:*** Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock.[1]

**Placing Electrodes:**
- Do not place the electrodes directly over an implanted device.
- Place the electrode pad at least one inch from any implanted device.

***CAUTION:*** Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

***CAUTION:*** Serial Communication Cable
The serial communication cable is only for use with the AED; it is not to be used with a telephone.

***CAUTION:*** Systems Statement
Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 601-1-1.

***CAUTION:*** Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

[1] *Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.*

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# SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.

Attention!: Identifies important information in this manual, on the AED, or on its component parts regarding the safe and proper use of the AED.

Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the electrodes, can withstand the effects of an externally applied defibrillation shock.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

**IP24** The AED is protected against the effects of splashing water in accordance with IEC 60529.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

International symbol for ON. Open the lid to turn on the AED.

Open the lid to turn ON the AED.

Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.

Check electrodes. The electrodes are missing, not connected or have compromised functionality.

Indicates AED requires maintenance by authorized service personnel.

When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.

When the **CONTINUE** indicator is lit, push this button to clear the internal memory to allow storage of new rescue data in the AED.

# SYMBOL DESCRIPTIONS (CONT.)

A red indicator with a BLACK X means the Responder AED requires operator attention or maintenance, and is not RescueReady. This symbol will be referred to as **RED** in the remainder of this manual.

A green indicator without a BLACK X means the Responder AED is RescueReady. This symbol will be referred to as **GREEN** in the remainder of this manual.



Use electrodes by this date; install battery by this date.




Expiration Date. Replace by this date.

Date of manufacture.

Latex Free.

Disposable. Single patient use only.

Tear here to open.

Do not recharge battery.

Position of electrodes on the chest of patient.

For use by or on the order of a Physician, or persons licensed by state law.

Dispose of properly in accordance with all state, province, and country regulations.

Do not incinerate or expose to open flame.

Explosion Hazard: Do not use in the presence of a flammable gas, including concentrated oxygen.

Upper and lower temperature limits.

Device Model Number

Serial Number

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Lot Number

Option Number

Lithium Sulfur Dioxide

Serial Communication Port

Additional information is provided in the AED Manual.

Points to important information regarding the use of the AED.

Lift Here

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# SECTION 2 - INTRODUCTION

# OVERVIEW

This section presents information about the AED, its use, and the training requirements for operation.


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# AED DESCRIPTION

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's electrodes to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. The AED uses one button and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators.

# INDICATIONS FOR USE

The AED with STAR Biphasic Waveform is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

# RHYTHMX® AED ECG ANALYSIS ALGORITHM

The RhythmX AED ECG analysis algorithm provides superior ECG detection capabilities, allowing it to be placed on patients at risk for sudden cardiac arrest. The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate
- Continuous Monitoring

## DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is programmable between 120 bpm (beats per minute) and 240 bpm via MDLink Software by the Medical Director. The default Detection Rate is 160 bpm. The Responder AED detection rate is 160 bpm.

## ASYSTOLE THRESHOLD

The asystole peak-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as Asystole and will not be shockable.

## NOISE DETECTION

The AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt "*ANALYSIS INTERRUPTED. STOP PATIENT MOTION*" to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

## NON-COMMITTED SHOCK

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt "*RHYTHM CHANGED. SHOCK CANCELLED.*" The AED will override the charge and continue ECG analysis.

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## SYNCHRONIZED SHOCK

The AED is designed to synchronize shock delivery on the R-wave. The AED will automatically attempt to synchronize to the R-wave. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

## PACEMAKER PULSE DETECTION

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

## SVT DISCRIMINATORS

The Responder AED is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the Responder AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT", however the Medical Director can enable this feature using MDLink on the Responder AED.

## SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable between 160 and 300 bpm or, “NO THERAPY FOR SVT” can be selected via MDLink Software by the Medical Director on the Responder AED only.

## CONTINUOUS MONITORING

***Responder AEDs are supplied with the Continuous Monitoring disabled. This is the factory default setting.***

The Responder AED can monitor the ECG rhythms continuously throughout the rescue including during Charge and CPR mode. Continuous Monitoring will interrupt CPR if a shockable rhythm is detected. When CPR is interrupted, the prompt, “DO NOT TOUCH PATIENT. ANALYZING RHYTHM” will be issued. Only one false interruption will be allowed during a single rescue cycle. CPR mode will not be interrupted if preceded by three consecutive shocks. The factory default setting for Continuous Monitoring in CPR is disabled, however the Medical Director can enable/disable this feature via MDLink software.

# RESCUE PROTOCOL

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1] and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the **SHOCK** button to deliver a series of up to 3 defibrillation shocks followed by performing 1 minute of CPR.

The 3 defibrillation shocks are delivered in a pre-programmed sequence.

***Note:*** The CPR protocol can be modified, for example from 1 to 3 minutes, in increments of 5 seconds, so CPR may be administered if the first analysis is non-shockable or following two consecutive non-shockable analysis decisions.

# STAR BIPHASIC WAVEFORM

The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the Responder AED are available in three different defibrillation shock[2] configurations. See table on next page and page 48 for additional information.
See next page.

# STAR BIPHASIC ENERGY PROTOCOLS FOR RESPONDER AED

The patented STAR® Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 20-180 Ohms. The Responder AED comes equipped with five different FDA-cleared biphasic energy protocols.

The operator, with guidance, direction and implementation from its designated AED program Medical Director, may select from one of these five protocols when placing the Responder AED into service. The Responder AED's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal). The accuracy of the energy for the energy in a 50 Ohm resistor is ±15%.

[1] *"Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" American Heart Association; 2000. Suppl. Circulation 102(8). August 22, 2000*

[2] *The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.*

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These protocols are selected by using our MDLink software program. The five biphasic energy protocols available are as follows:

| Energy Protocols | Shock Sequence[1] | Energy Level | Energy Range (J) |
|---|---|---|---|
| Factory Default | 1. | 200VE | 140J-250J |
| | 2. | 300VE | 190J-360J |
| | 3. | 300VE | 190J-360J |
| Protocol #2 | 1. | 200VE | 140J-250J |
| | 2. | 200VE | 140J-250J |
| | 3. | 300VE | 190J-360J |
| Protocol #3 | 1. | 150VE | 105J-195J |
| | 2. | 200VE | 140J-250J |
| | 3. | 200VE | 140J-250J |
| Protocol #4 | 1. | 150VE | 105J-195J |
| | 2. | 150VE | 105J-195J |
| | 3. | 200VE | 140J-250J |
| Protocol #5 | 1. | 200VE | 140J-250J |
| | 2. | 200VE | 140J-250J |
| | 3. | 200VE | 140J-250J |

[1] *The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.*

# OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the AED must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the AED.
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

***Notes:*** Keep valid certificates of training and certification as required by state, province, or country regulations.

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# SECTION 3 - GETTING STARTED

# OVERVIEW

This section presents information on unpacking and setting up the AED


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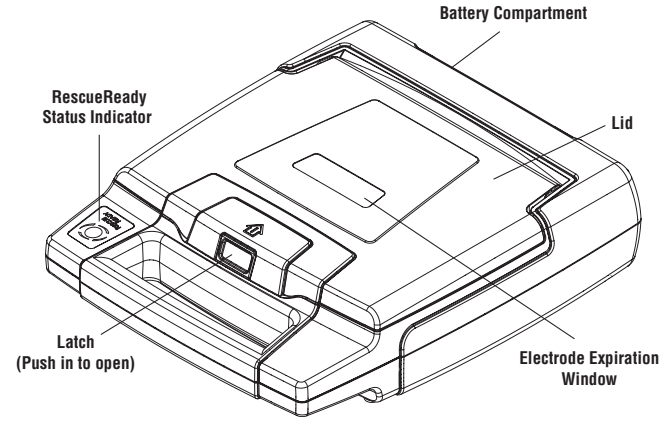
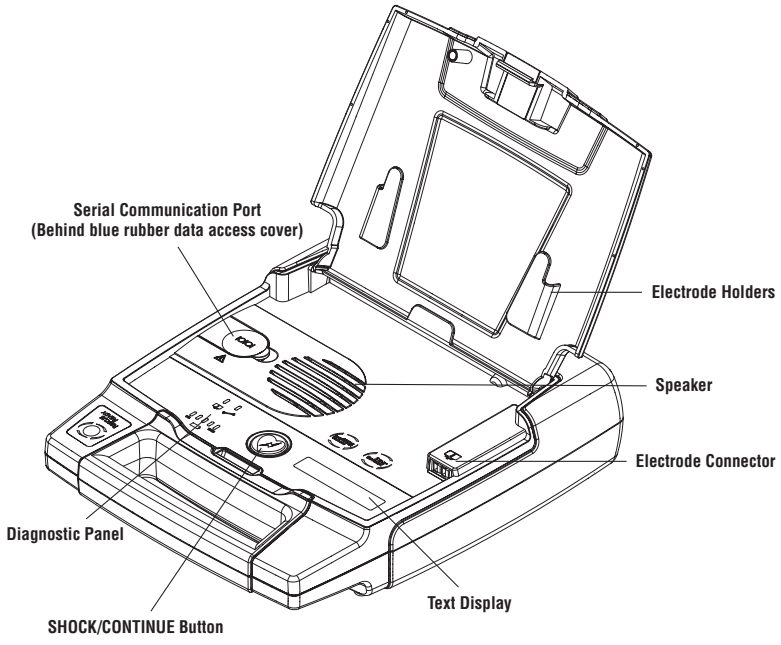
# UNPACKING AND INSPECTING

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

# AED PARTS

The following drawings show the AED parts and their locations.



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## THE AED HAS THREE MODES:

**Operating Mode:** Defined as having the battery installed and the lid open. This is the mode the AED would be in during an actual rescue situation.

**Standby Mode:** When the battery is installed, but the lid is closed. In this mode the AED is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

**Storage Mode:** When the battery is removed, such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.

## ENVIRONMENTAL OPERATING AND STANDBY CONDITIONS

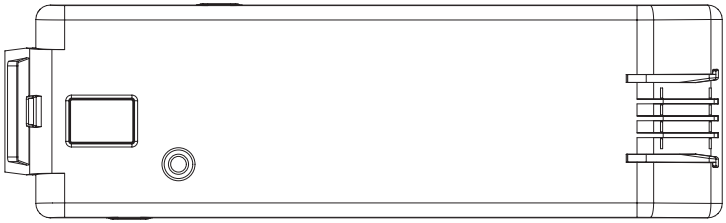
See Section 7 – Technical Data, Parameters, Environmental Operation and Standby Conditions on page 48.

⚠ ***CAUTION:*** Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self test determines environmental conditions outside of the AED's operating parameters for 5 consecutive days, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once.
See Section 7 – Technical Data, Parameters, Operation and Standby Conditions on page 48.

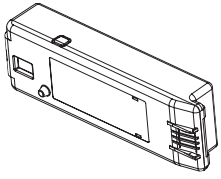
## SHIPPING AND TRANSPORT CONDITIONS

(For up to 1 week)
See Section 7 – Technical Data, Safety and Performance Standards/Shipping and Transportation Conditions on page 52.

# INTELLISENSE BATTERY



The Responder AED IntelliSense battery technology offers you the most advanced battery capabilities available for defibrillators. Responder AED IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operating life. The actual battery history can be reviewed using the RescueLink software.
This history includes:



- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges completed
- Time in Operation (hours:minutes)
- Days of Standby Operation
- Battery Capacity Remaining

## BATTERY OPERATING LIFE

The battery operating life depends on the type of battery (9142 for Responder AED ), actual usage and environmental factors.

The following table represents the expected life of the Responder AED when used in Standby Mode.

| Model | Estimated Shelf Life | Warranty | Typical Shocks |
|---|---|---|---|
| 9142 Lithium | 5 Years | 3 Years | up to 290 shocks |

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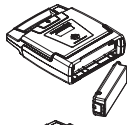
## BATTERY SHELF LIFE

The Responder AED batteries have a shelf-life of five years. Shelf-life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

***Note:*** Storing the battery outside its specific range (0-50°C) will decrease battery life.

## BATTERY INSTALLATION



1. With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.

2. Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED case.

3. For the Responder AED, open the lid for 5 seconds to initiate self test. If the battery is installed properly, the **STATUS INDICATOR** will turn **GREEN**. Close the lid.

***WARNING:*** Battery is Not Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

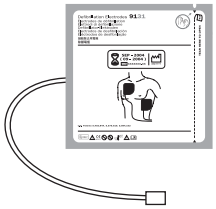
***CAUTION:*** Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

***CAUTION:*** Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

***CAUTION:*** Use only General Electric Approved Equipment
Using batteries, electrodes, cables, or optional equipment other than those approved by General Electric may cause the Responder AED to function improperly during a rescue.

***CAUTION:*** Possible Improper AED Performance
Using electrodes that are damaged or expired may result in improper AED performance.

# ELECTRODES



The defibrillation electrodes come in a ready-to-use, sealed package containing pair of self-adhesive electrodes with an attached cable and connector. The electrodes are disposable and should be discarded after each rescue.

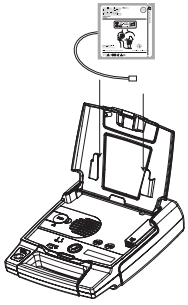
The electrodes have a limited shelf-life and should not be used beyond the expiration date. Keep a fresh, unopened pair of electrodes plugged into the AED at all times. Refer to the electrode package label for operation temperatures.

On the Responder AED, an audible and visual alert will indicate after the self-test if the electrodes are missing, unplugged or damaged.

⚠ ***CAUTION:*** Possible Improper AED Performance

Using electrodes that are damaged or expired may result in improper AED performance.

## ELECTRODE INSTALLATION



1. Open the lid of the AED.
2. Place the electrode package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the electrodes will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), then plug the electrode connector into the AED case as shown in the drawing.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the electrode package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid. Make sure that the **STATUS INDICATOR** is **GREEN**.

⚠ ***CAUTION:*** Use only Approved Equipment
Using batteries, electrodes, cables, or optional equipment other than those approved by General Electric may cause the AED to function improperly during a rescue.

⚠ ***CAUTION:*** Possible Improper AED Performance
Using electrodes that are damaged or expired may result in improper AED performance.

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## DIRECTIONS FOR USE:

1. Do NOT open until ready to use, short term use only.
2. Ensure the skin site is clean and dry.
3. Separate one electrode from liner.
4. Place one electrode on skin in either direction.
5. Peel and place remaining electrode.

# AED INDICATORS

The following indicators are located on the AED.

The **STATUS INDICATOR** is located on the Responder AED handle. When this indicator is **GREEN**, the device is RescueReady. This means the Responder AED self-tests have verified the following:

- Battery has an adequate charge.
- Electrodes are properly connected to the Responder AED and in working order.
- Integrity of the internal circuitry is good.

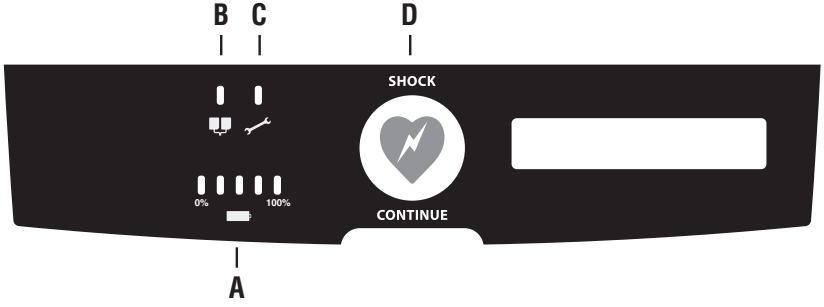
When the **STATUS INDICATOR** is **RED**, maintenance is required.

## AUDIBLE MAINTENANCE INDICATOR

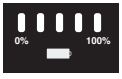
When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

## DIAGNOSTIC PANEL

A **SMARTGAUGE BATTERY** Indicator
B **ELECTRODES** Indicator
C **SERVICE** Indicator
D **SHOCK/CONTINUE** Button




## SMARTGAUGE™ BATTERY STATUS INDICATOR




The **SMARTGAUGE** Battery Status Indicator has five (5) LEDs, four (4) green and one (1) red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases. When the green LEDs go out and the red LED lights up, replace the battery.

***Note:*** When the red LED initially lights up – upon lid opening or at any time during a rescue – a "*BATTERY LOW*" prompt will be issued at once. However, the AED is capable of delivering at least 9 more defibrillation shocks after the first "*BATTERY LOW*" prompt is issued.

When the AED battery cannot deliver any more shocks, it continuously repeats the "*BATTERY LOW*" voice prompt. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon opening the lid.

## ELECTRODES INDICATOR

The **ELECTRODES** LED lights up when the electrodes are:

- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged). This feature applies to the Responder AED only.
- Disconnected from the patient during a rescue.

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## SERVICE INDICATOR

The **SERVICE** LED lights up when the AED requires maintenance that can only be performed by qualified service personnel.

## SHOCK/CONTINUE BUTTON

The AED has one button called the **SHOCK/CONTINUE** button.
This button is located on the diagnostic panel and serves two functions:

- Delivers a defibrillation shock.
- Clears the internal memory of previous rescue data so that new rescue data can be stored.

## SHOCK INDICATOR

The word **SHOCK** and the shock button indicator LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

## CONTINUE INDICATOR

The word **CONTINUE** will illuminate yellow and the continue button indicator LED will illuminate red when the previous rescue data has not been cleared from the internal memory.

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

***Note:*** There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

# SETTING THE AED INTERNAL CLOCK

The internal clock is preset at Central Standard Time (GMT - 6 hours) and should be reset to the correct date and local time. The AED will automatically adjust itself for Daylight Savings Time. This feature can be turned off using the MDLink software. To set the clock, you will need a Windows 98 or newer PC, RescueLink software installed, and the AED serial cable connected to the PC.

**To set the clock settings:**

- Ensure that the PC is set at the correct local time and date.
- Open the lid of the AED and run the RescueLink software on the PC.
- Connect the cable to the serial port on the AED.
- Verify that the voice prompt states "*Communications Mode*".
- Click **COMMUNICATIONS** on the main menu. Select **AED DATE AND TIME**.
- Click on the **GET** button to review the current time in the AED.
- If the time and date is incorrect, click **SET** to set new time and date. The AED date and time will automatically be updated to the PC's time and date.

# VOICE PROMPTS AND TEXT DISPLAY

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The Responder AED text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| *"Tear Open Electrode Package and Remove Electrodes."* | *OPEN PACKAGE AND REMOVE ELECTRODES* | When the lid is opened, this phrase is repeated twice to initiate the rescue sequence. |
| *"Peel One Electrode from Plastic Liner."* | *PEEL ELECTRODE FROM PLASTIC LINER* | Repeats until one electrode is peeled off of the liner. |
| *"Place One Electrode on Bare Upper Chest."* | *PLACE ELECTRODE ON UPPER CHEST* | Repeat twice while one electrode is placed. |
| *"Peel Second Electrode and Place on Bare Lower Chest as Shown."* | *PLACE ELECTRODE ON LOWER CHEST* | Repeats until both electrodes are placed on the patient. |
| *"Do Not Touch Patient! Analyzing Rhythm."* | *DO NOT TOUCH PATIENT ANALYZING RHYTHM* | When the AED is analyzing the cardiac rhythm of the patient. |
| *"Shock Advised."* | *SHOCK ADVISED* | When the AED is preparing to deliver a defibrillation shock. |
| *"Charging."* | *CHARGING* | Repeated while AED is charging. |

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| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| *"Stand Clear! Push Flashing Button to Deliver Shock."* | *STAND CLEAR PUSH BUTTON TO SHOCK* | After the AED is fully charged and ready to deliver the defibrillation shock. The RED **SHOCK** indicator flashes and the phrase repeats for 30 seconds or until the **SHOCK** button is pushed. |
| *"Check for Breathing. If Not Breathing, Give Patient Two Breaths."* | *IF NOT BREATHING GIVE TWO BREATHS* | • After the AED delivers 3 consecutive defibrillation shocks<br>• After the AED detects a non-shockable cardiac rhythm.<br>• When 2 1/2 minutes or more has elapsed since CPR was last administered<br>• Note: This prompt may be disabled in MDLink, |
| *"Check for Signs of Circulation. If No Circulation, Start CPR."* | *IF NO CIRCULATION, START CPR* | • After previous prompt or if previous prompt is disabled<br>• After the AED delivers 3 consecutive defibrillation shocks<br>• After the AED detects a non-shockable cardiac rhythm during cardiac rhythm analysis<br>• When 2 1/2 minutes or more has elapsed since CPR was last administered |
| *"Check Electrodes"* | *CHECK ELECTRODES* | Occurs when patient impedance is too low or too high. |
| *"Battery Low"* | *BATTERY LOW* | Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the phrase repeats continuously. You must replace the battery before continuing with the rescue. If completely depleted, all AED activity will terminate. |
| *"Analysis Interrupted. Stop Patient Motion."* | *ANALYSIS INTERRUPTED STOP PATIENT MOTION* | When the AED detects ECG noise artifact, stop moving or touching the patient. Remove other electronic devices within a 5-meter radius. |
| *"Open Lid to Continue Rescue"* | *OPEN LID TO CONTINUE RESCUE* | When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds. |
| *"Rhythm Changed. Shock Cancelled."* | *RHYTHM CHANGED. SHOCK CANCELLED* | When the AED detects a change in rhythm – when the device is prepared to shock. |
| *"Data in memory. Push Flashing Button to Erase Data and Perform Rescue."* | *DATA IN MEMORY PUSH BUTTON TO ERASE* | When there is a previously stored rescue in internal memory, the yellow **CONTINUE** button will flash and the phrase will repeat. |
| *"Remove Cable to Continue Rescue."* | *REMOVE CABLE* | The message can be cleared by pressing the **SHOCK/CONTINUE** button to erase the internally stored rescue data or retrieving the rescue data with RescueLink and erasing the stored data with RescueLink. When a serial communication cable is connected to the AED during a rescue, the phrase repeats until the cable is disconnected. |

| VOICE PROMPT | TEXT DISPLAY | SITUATION |
|---|---|---|
| *"Communications Mode"* | *COMMUNICATIONS MODE* | When the lid is open and the serial communication cable is plugged into the AED. |
| *(Beep)* | | "One Beep" occurs in 15-second intervals during CPR when enabled by the MDLink software program, "Warble Beep" occurs when the AED requires maintenance. |
| *"Continue CPR"* | *CONTINUE CPR* | During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing. |
| *"Service Required"* | *SERVICE REQUIRED* | Occurs after the self-tests determine that the AED is not functioning properly. The prompt "*SERVICE REQUIRED*" will be heard when the lid is opened. The red **SERVICE** indicator will illuminate and "*SERVICE REQUIRED*" will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted. |

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# SECTION 4 – INSTRUCTIONS FOR USE

## OVERVIEW

This section presents information about how to use the AED to perform a rescue.


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| Step 3: Shock Delivery and CPR Mode | 36 |
| Step 4: Post Rescue | 37 |
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# STEP 1: ASSESSMENT AND ELECTRODE PLACEMENT

## PREPARATION

Determine that the patient is over 8 years of age or weighs more than 55 pounds (25 kg) and exhibits the following:

The patient is unresponsive, and
The patient is not breathing.

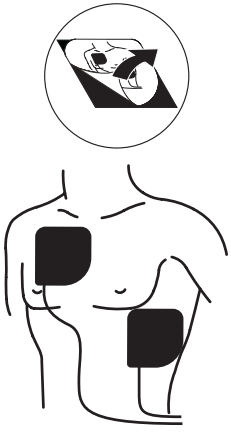
Remove clothing from the patient's chest. Ensure the skin site is clean and dry. Dry the patient's chest and shave excessive hair if necessary.

Open the AED lid and wait until the LEDs are lit.

***Note:*** When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric electrodes for procedure on changing adult electrodes to pediatric.

## PLACE ELECTRODES

The AED will issue the prompt "*Tear Open Electrode Package and Remove Electrodes.*" Keep the electrodes connected to the AED, tear the electrode package along the dotted line and remove the electrodes from the package. Leave the package attached to the electrode wires.



After the prompt "*Peel One Electrode From Plastic Liner*," with a firm, steady pull, carefully peel one electrode away from the release liner.

Then, after the prompt "*Place One Electrode on Bare Upper Chest*," place the electrode with the sticky side of on the patient's skin on the upper right chest, placing the top of the electrode on the collarbone. Avoid placing the electrode directly over the sternum.

Finally, after the prompt "*Peel Second Electrode and Place on Bare Lower Chest As Shown*," pull the second electrode from the release liner and place it on the lower left chest, below and left of the breast.

***Note:*** Responder AEDs standard defibrillation electrodes are non-polarized and can be placed in either position as shown on the electrode package. When using pacing/monitoring electrodes, refer to placement instructions on the pacing/monitoring electrode package.

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When the electrodes are placed, the voice prompt will say *"Do Not Touch Patient. Analyzing Rhythm."* If the electrodes are not properly placed or become disconnected at any time during the rescue, the voice prompt *"Check Electrodes"* will be heard. When this occurs, ensure that:

Electrodes are firmly placed on clean, dry skin
Electrode cable is securely plugged into the AED

# STEP 2: ECG ANALYSIS

As soon as the AED detects proper electrode placement, the voice prompt "*Do Not Touch Patient. Analyzing Rhythm."* will be heard. The AED will begin to analyze the cardiac rhythm of the patient.

If a shock is advised, the voice prompt will say, *"Shock Advised. Charging."* When the AED is ready to deliver a defibrillation shock, the **SHOCK** button will flash and the prompt, *"Stand Clear. Push Fashing Button to Deliver Shock"* will be heard. The tone, flashing button, and voice prompt will continue until the shock is delivered or change in rhythm is detected, or 30 seconds elapse.

When the AED is charged, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer needed, the AED will issue the prompt *"Rhythm Changed. Shock Cancelled,"* disarm and reanalyze.

If no shock is advised, the AED will prompt to start CPR with the prompt *"Check for Breathing. If Not Breathing, Give Patient Two Breaths" (if this prompt is enabled) then "Check for Signs of Circulation. If No Circulation, Start CPR."*

If noise is detected during analysis, the AED will warn you with the prompt *"Analysis Interrupted. Stop Patient Motion"* and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 5 meters). Remove the electronic device or stop the excessive motion when you hear this prompt.

# STEP 3: SHOCK DELIVERY AND CPR MODE

When the AED is ready to deliver a defibrillation shock, the **SHOCK** button will flash and the prompt "*Stand Clear. Push Flashing Button to Deliver Shock*" will be heard.

Make sure no one is touching the patient and push the **SHOCK** button to deliver a defibrillation shock. If you do not push the **SHOCK** button within 30 seconds of hearing the prompt, the AED will disarm and reanalyze the cardiac rhythm.

After the AED delivers the first defibrillation shock, it reanalyzes the patient's rhythm to determine if the shock was successful. If the AED determines that a shockable cardiac rhythm still exists, it will continue to guide you through additional shocks as needed following the AHA and ILCOR protocols.

***Note:*** During a rescue, the text screen displays voice prompts, elapsed time of rescue and number of shocks delivered.

## CPR MODE

After delivery of three consecutive defibrillation shocks or detection of a non-shockable rhythm, the AED automatically enters CPR mode.
The voice prompt will say, *"Check for Breathing. If Not Breathing, Give Patient Two Breaths" (if this prompt is enabled) then "Check for Signs of Circulation. If No Circulation, Start CPR."* Perform CPR if the patient is not responsive and not breathing.

During this time-out for CPR, the Responder AED can continue to monitor the patient's heart rhythm. If the patient's condition changes and the Responder AED detects a shockable rhythm during the CPR period, the voice prompt will say, "*Do Not Touch Patient. Analyzing Rhythm.*" This feature is disabled, but can be enabled in MDLink by the Medical Director.

After delivery of three consecutive defibrillation shocks, the AED automatically enters a mandatory CPR time-out period. During this time-out, the AED will not interrupt the CPR mode if the patient's condition changes and the AED detects a shockable rhythm. After the CPR time-out period has expired, the voice prompt "*Do Not Touch Patient. Analyzing Rhythm.*" will be heard.

***Note:*** During CPR mode, the text screen displays a countdown timer.

If the patient is conscious and breathing normally, leave the electrodes on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support [ALS] personnel to arrive. Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director.

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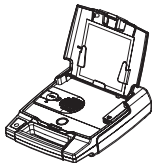
# STEP 4: POST RESCUE

After transferring the patient to ALS personnel, prepare the AED for the next rescue:



1. Retrieve the rescue data stored in the internal memory of the AED by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Erase the internal memory of the AED.
3. Connect a new pair of electrodes to the AED.
4. Close the lid.
5. Verify that the **STATUS INDICATOR** on the Responder AED handle is **GREEN**.

# WARNINGS

The following cautions must be observed to prevent problems during the rescue.

***DANGER***: Fire and Explosion Hazard
Exercise caution when operating the AED close to flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

***WARNING:*** Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation electrodes clear of other electrodes or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

***WARNING:*** Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

***WARNING:*** Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

***CAUTION:*** Use only Approved Equipment
Using batteries, electrodes, cables, or optional equipment other than those approved by General Electric may cause the Responder AED to function improperly during a rescue.

***CAUTION:*** Possible Improper AED Performance
Using electrodes that are damaged or expired may result in improper AED performance.

***CAUTION:*** Serial Communication Cable
The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove cable to continue rescue" will be heard until you remove the serial communication cable from the AED

***CAUTION:*** Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

***CAUTION:*** Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock.

**Placing Electrodes:**
- Do not place the electrodes directly over an implanted device.
- Place the electrode pad at least on inch from any implanted device.

***CAUTION:*** Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

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# SECTION 5 – DATA MANAGEMENT

# OVERVIEW

The AED is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.


| **Topic** | **Page #** |
|---|---|
| Recording Rescue Data | 39 |
| Review Rescue Data | 39 |


# RECORDING RESCUE DATA

## RECORDING DATA IN INTERNAL MEMORY

The AED automatically stores up to 34 minutes of rescue data.

If the internal memory contains a previously stored rescue when a rescue is attempted, the voice prompt *"Data in Memory. Push Flashing Button to Erase Data and Perform Rescue"* will be heard. Pressing the **CONTINUE** button will erase the data and allow the rescue attempt to continue.

***Note:*** Do not press the **CONTINUE** button unless you are sure you want to erase the internal memory in the AED.

# REVIEWING RESCUE DATA

## RETRIEVING DATA FROM MEMORY

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the blue rubber data access cover. The voice prompt will say "*Communications Mode."*
3. Run the RescueLink software program.
4. Select COMMUNICATIONS, GET RESCUE DATA. On the RescueLink software program.
6. Select INTERNAL MEMORY OF AED then select OK.

***WARNING:*** Electric Shock and Fire Hazard
Do not connect any telephones or unauthorized connectors to the socket on this equipment.

***CAUTION:*** Serial Communication Cable
The serial communication cable is only for use with the AED; it is not to be used with a telephone.

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# SECTION 6 – MAINTENANCE & TROUBLESHOOTING

## OVERVIEW

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.


| **Topic** | **Page #** |
|---|---|
| Self-Tests | 41 |
| Indicator Troubleshooting Table | 42 |
| Scheduled Maintenance | 43 |
| Authorized Repair Service | 44 |
| Frequently Asked Questions | 45 |


## SELF-TESTS

The AED has a comprehensive self-test system that automatically tests the electronics, battery, electrodes, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

These self-tests eliminate the need for in depth periodic / annual maintenance testing. The comprehensive self-tests insure that the Responder AED is RescueReady®, with minimal user involvement and maintenance costs. Once a month during the daily self-tests, the AED performs a full charge of the capacitors. During this test the AED monitors the charge time, voltage level and proper discharge function. When the Responder AED requires maintenance, audible and/or visual indicators are activated. By monitoring the visual and audible indicators, the user can be assured that the Responder AED is ready to conduct a rescue.

When performing the self-tests, the AED completes the following steps automatically.

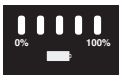
- Turns itself ON, and the **STATUS INDICATOR** changes to **RED**.
- Performs the self-test.
- If successful, the **STATUS INDICATOR** reverts to **GREEN**.
- Turns itself OFF if the lid is closed.

There are three types of automatic self-tests. The Daily Self-Test checks the battery, electrodes, and the electronic components. The Weekly Self-Test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-Test. During the Monthly Self-Test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the **STATUS INDICATOR** will remain **RED**. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

# INDICATOR TROUBLESHOOTING TABLE

The following is a troubleshooting table for the AED indicators.

| VIEW | SYMPTOM | SOLUTION |
|---|---|---|
| | Red **SERVICE** indicator (LED) is lit. | Maintenance by authorized service personnel is required. Call GEMS IT (see page 4) or your local distributor. |
| | Red **ELECTRODES** indicator (LED) is lit. | Connect the electrodes or replace with a new pair. |
|  | The last battery indicator (LED) is red. | The battery is low. Replace with a new battery. |
| | **STATUS INDICATOR** is **RED**, and no other indicators on the diagnostic panel are lit. | The battery power is completely depleted. Replace with a new battery. If **STATUS INDICATOR** remains **RED**, refer to the Responder AED for maintenance. Call GEMS IT Customer Service or your local distributor. |

***CAUTION:*** Temperature/Humidity/Pressure Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self test verifies the impact of extreme environmental conditions on the AED by checking temperature, humidity and pressure; if the daily self test determines environmental conditions outside of the AED's operating parameters for 5 consecutive days, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions on page 48.

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# SCHEDULED MAINTENANCE

## DAILY MAINTENANCE

Check the **STATUS INDICATOR** to ensure that it is **GREEN**. When the indicator is **GREEN**, the Responder AED is ready for a rescue. If the indicator is **RED**, refer to the Troubleshooting Table in this chapter.

## MONTHLY MAINTENANCE

1. Open the AED lid.
2. Wait for the AED to indicate status:
   Observe the change of the **STATUS INDICATOR** to **RED**. After less than 5 seconds, verify that the **STATUS INDICATOR** returns to **GREEN**.
3. Observe the expiration date on the electrodes.
4. Listen for the voice prompts.
5. Close the lid and confirm that **STATUS INDICATOR** remains **GREEN**.

## ANNUAL MAINTENANCE

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

**Check the Integrity of the Electrodes and Circuitry**

1. Open the AED lid.
2. Remove the electrodes.
3. Close the lid.
4. Confirm that the **STATUS INDICATOR** turns red.
5. Open the lid and confirm that the **ELECTRODE** indicator is lit.
6. Reconnect the electrodes and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid.
   Check to make sure that the **STATUS INDICATOR** is **GREEN.**
8. Open the lid and confirm that no diagnostic indicators are lit.
9. Check the expiration date of the electrodes; if expired, replace them.
10. Check the electrode's packaging integrity.
11. Close the lid.

**Check the Integrity of the Service Indicator (LED) and Circuitry**

1. Immediately after opening the AED lid, press and hold the **SHOCK/CONTINUE** button and confirm that the **SERVICE** LED is lit.
2. Release the **SHOCK/CONTINUE** button.
3. Close the lid.
4. Verify that the **STATUS INDICATOR** returns to **GREEN**.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.

**Check the Integrity of the Case**

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact GEMS IT Customer Service at one of the following telephone numbers: +49.761.4543.0 (Europe), +61.2.9975.5501 (Australia), +852.2100.6300 (Hong Kong), +65.277.7620 (Southeast Asia), or contact your local GEMS IT distributor.

**Cleaning the AED Case**

Gently clean the surface of the AED case with a damp sponge or with a cloth and mild soap.

***CAUTION:*** Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

No periodic safety analysis tests referred to by the IEC 601-1 international standard are required.

# AUTHORIZED REPAIR SERVICE

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact GEMS IT Customer Service.

***WARNING:*** Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to GEMS IT authorized service personnel.

***Note:*** The warranty will be void upon unauthorized disassembly or service of the AED.

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# FREQUENTLY ASKED QUESTIONS

## QUESTIONS AND ANSWERS

1. Q: *Can I give CPR while the AED is analyzing?*
   A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

2. Q: *Can I transport the victim while the AED is analyzing?*
   A: No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

3. Q: *Do I need to prepare the chest prior to electrode application?*
   A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. Follow your Medical Director's instruction.

4. Q: *What happens if the battery is low when I begin a rescue?*
   A: When the battery indicator is red, the AED issues a "*Battery Low*" prompt once; however, the AED is still capable of delivering approximately 9 more defibrillation shocks.

   When the AED is not capable of delivering any more shocks, it continuously repeats the "*Battery Low*" prompt. To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED will begin to record the events from then on as a separate rescue.

5. Q: *How do I set the AED internal clock?*
   A: Set the clock by using the RescueLink Software Program and a PC. See Setting the AED Internal Clock in Chapter 3.

6. Q: *What happens if I close the lid in the middle of a rescue attempt?*
   A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, *"Open Lid to Continue Rescue."* If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

   ***Note:*** If the lid is closed during a rescue while the electrodes are connected to the patient, the **STATUS INDICATOR** may turn **RED**. When the lid is reopened, however, the rescue may be continued even though the **STATUS INDICATOR** remains **RED**.

7. Q: *My AED is sounding an audible alert. Why? How do I stop it?*
   A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the **STATUS INDICATOR** will remain **RED**.

8. Q: *When I open the lid, why do I get the voice prompt "Data in Memory. Push Flashing Button to Erase Data and Perform Rescue." How to I get the message to stop occurring?*
   A: This message occurs when there is a previously stored rescue in the internal memory of the AED. You can clear the message by:

   1. Pressing the **SHOCK/CONTINUE** button to erase the internally stored rescue data OR
   2. Retrieving the rescue data with RescueLink and erasing the stored data with RescueLink.

9. Q: *The AED did not sound an audible alert when I removed the electrodes and closed the lid. Why?*
   A: The lid-closed electrode self-test only activates the **STATUS INDICATOR**. The AED allows time for replacement of the electrodes – as removing electrodes is a normal procedure after a rescue - or a battery during the post rescue procedure, however, an audible maintenance indicator will be triggered after the next Daily Self-Test.

10. Q: *What can I do to keep the AED warm when a rescue is in an isolated area and at subzero temperatures?*
    A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the electrodes and the battery warm.

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# SECTION 7 – TECHNICAL DATA

# OVERVIEW

This section presents technical data about the AED.


| Topic | Page # |
|---|---|
| Parameters | 47 |
| Safety and Performance Standards | 50 |
| STAR Biphasic Waveform | 52 |
| RHYTHMx ECG analysis performance | 54 |


# PARAMETERS

## OPERATION

Semi-Automatic (shock advisory)

## AUDIBLE ALERTS

Voice Prompt
Maintenance Alert

## VISIBLE INDICATORS

Status Indicator
Battery Status Indicator
Service Indicator
Electrodes Indicator
Text Display

## RESCUE DATA STORAGE

| Storage | Capacity |
|---|---|
| Internal | 34 minutes ECG data with event annotation |

## DIMENSIONS

| Measurement | Dimension |
|---|---|
| Height | 8 cm (3.3 in) |
| Width | 27 cm (10.6 in) |
| Depth | 31 cm (12.4 in) |

## WEIGHT

| Model | Weight with Batteries and Electrodes |
|---|---|
| 9300 | 3.10 kg (6.6 lb) |

## ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

| Atmosphere | Condition |
|---|---|
| Temperature | 0°C to 50°C (32°F to 122°F) |
| Humidity | 5% to 95% (non-condensing) |
| Pressure | 57kPa (+15,000ft) to 103kPa (-500ft) |

## SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

| Atmosphere | Condition |
|---|---|
| Temperature | -30°C to 65°C (-22°F to 149°F) |
| Humidity | 5% to 95% (non-condensing) |
| Atmospheric Pressure | 57kPa (+15,000ft) to 103kPa (-500ft) |

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## ELECTRODES

- Self-adhesive, disposable defibrillation electrodes
- Minimum combined surface area: 228cm$^2$
- Extended length of lead wire: 1.3m

## LITHIUM BATTERY SPECIFICATIONS

- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

| Model | Estimated Shelf Life | Warranty | Typical Shocks |
|---|---|---|---|
| 9142 Lithium | 5 Years | 3 Years | up to 290 shocks |

The battery operating life depends on the type of battery (9142 for Responder AED), actual usage and environmental factors.

## BATTERIES AND CAPACITOR CHARGE TIMES

A new battery typically takes 10 seconds to charge the AED to maximum energy.

A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds for a new rescue.
The maximum time from “Analyze” to “Ready to Shock” is 22 seconds for a new rescue.

## DELIVERY OF THREE DEFIBRILLATION SHOCKS

55 seconds (nominal)

## AED SELF-TEST SEQUENCE

| Frequency of Self-Test | What is Tested? |
|---|---|
| Daily | Battery, electrodes, internal electronics, **SHOCK/CONTINUE** button, and software (no charge). |
| Weekly | Battery, electrodes, internal electronics, **SHOCK/CONTINUE** button, and software (partial charge). |
| Monthly (every 28 days) | Battery under load, electrodes, internal electronics, full-energy charge cycle, **SHOCK/CONTINUE** button, and software (full charge). |
| Open Lid (when lid is opened) | Battery, electrodes, internal electronics, **SHOCK/CONTINUE** button, and software. |
| Close Lid (when lid is closed) | Battery, electrodes, internal electronics, **SHOCK/CONTINUE** button, and software. |

# SAFETY AND PERFORMANCE STANDARDS

## AED MODELS 9300

The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Responder AED Model 9300E and electrodes conform to the applicable requirements of the following:

CE
0123

**CE**
CE Marked by TUV Product Services 0123 per the Medical Device Directive 93/42/EEC of European Nations

**ETL**
Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

**Electrical, Construction, Safety and Performance**
IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
ANSI/AAMI DF-39 (1993)

**Electromagnetic Compatibility (EMC)**
IEC 60601-1-2 (2001)
IEC 60601-2-4 Section 36
ANSI/AAMI DF-39(1993) Section 3.3.21

The unit is safe for human use in compliance with the IEC 601-1 Safety Analysis Tests standard.

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## EMISSIONS

| Field | Models | Standard or Compliance |
|---|---|---|
| E-M | 9300 | IEC 55011/CISPR 11, Group 1, Class B |
| Magnetic | 9300 | ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker |

## IMMUNITY

| Field | Models | Standard or Compliance |
|---|---|---|
| E-M | 9300 | IEC 61000-4-3, Level X, (20V/m)<br>IEC 60601-2-4, Section 36.202.3 (20-V/m)<br>AAMI DF39, Section 3.3.21.2.1 |
| Magnetic | 9300 | IEC 61000-4-8 (2001)<br>IEC 60601-2-4 (2002), Section 36.202.8<br>AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz |
| ESD | 9300 | IEC 61000-4-2, Level 3<br>IEC 60601-2-4 (2002), Section 36.202.2<br>6KV contact discharge, 8KV air gap discharge |

## ENVIRONMENTAL CONDITIONS

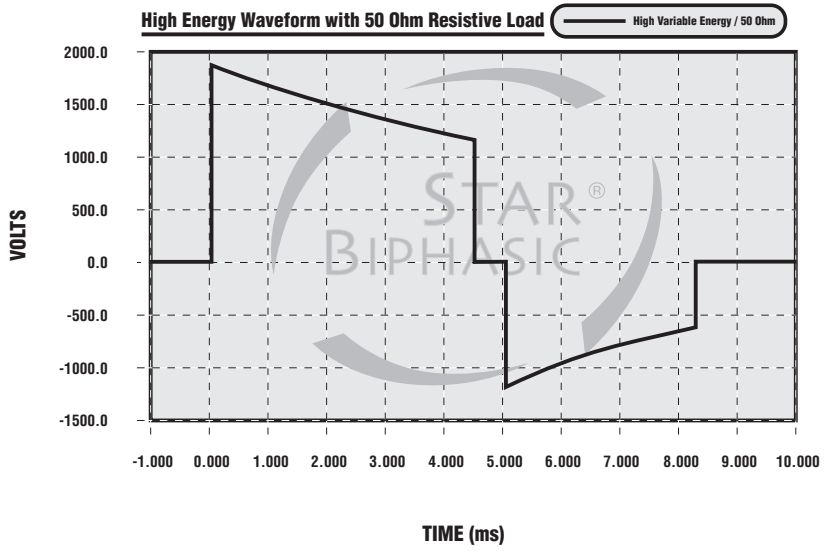
| Condition | Models | Standard or Compliance |
|---|---|---|
| Free Fall Drop | 9300 | IEC 60068-2-32 (1975) AM 2 (1990), 1 meter |
| Bump | 9300 | IEC 60068-2-29 (1987), 40g and 6000 bumps |
| Vibration (Random) | 9300 | IEC 60068-2-64 (1993): 10Hz –2KHz, 0.005 – 0.0012 $g^2$/Hz |
| Vibration (Sine) | 9300 | IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150 Hz, 2g |
| Enclosure Protection | 9300 | IEC 60529 (2001), IP24 |

## SHIPPING AND TRANSPORTATION CONDITIONS

ISTA Procedure 2A

# STAR BIPHASIC WAVEFORM

The waveform generated by the Responder AED is a BIPHASIC TRUNCATED EXPONENTIAL waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load. (See figure A1 and Tables A1through A3)




## FIGURE A1. STAR BIPHASIC WAVEFORM.

**Table A1 - Ultra-Low Variable Energy (150 VE) Waveform into Different Resistive Loads (Typical Values)**

| Patient's Impedance (Ohms) | Phase 1 Delivered Start Volts | Phase 1 Delivered End Volts | Phase 1 Duration (ms) | Phase 2 Delivered Start Volts | Phase 2 Delivered End Volts | Phase 2 Duration (ms) | Total Energy Delivered (J) |
|---|---|---|---|---|---|---|---|
| 25 | 1393V | 743V | 3.3 ms | 743V | 214V | 3.2 ms | 170J |
| 50 | 1420V | 909V | 4.5 ms | 909V | 479V | 3.2 ms | 150J |
| 75 | 1430V | 973V | 5.8 ms | 973V | 630V | 3.2 ms | 136J |
| 100 | 1434V | 1007V | 7.0 ms | 1007V | 724V | 3.2 ms | 127J |
| 125 | 1437V | 1027V | 8.3 ms | 1027V | 786V | 3.2 ms | 120J |
| 150 | 1439V | 1040V | 9.5 ms | 1040V | 830V | 3.2 ms | 115J |

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**Table A2 - Low Variable Energy (200VE) Waveform into Different Resistive Loads (Typical Values)**

| Patient's Impedance (Ohms) | Phase 1 Delivered Start Volts | Phase 1 Delivered End Volts | Phase 1 Duration (ms) | Phase 2 Delivered Start Volts | Phase 2 Delivered End Volts | Phase 2 Duration (ms) | Total Energy Delivered (J) |
|---|---|---|---|---|---|---|---|
| 25 | 1609V | 858V | 3.3 ms | 858V | 247V | 3.2 ms | 226J |
| 50 | 1640V | 1050V | 4.5 ms | 1050V | 553V | 3.2 ms | 200J |
| 75 | 1651V | 1124V | 5.8 ms | 1124V | 728V | 3.2 ms | 182J |
| 100 | 1656V | 1163V | 7.0 ms | 1163V | 835V | 3.2 ms | 169J |
| 125 | 1660V | 1186V | 8.3 ms | 1186V | 907V | 3.2 ms | 160J |
| 150 | 1662V | 1201V | 9.5 ms | 1201V | 959V | 3.2 ms | 153J |

**Table A3 - High Variable Energy (270VE) Waveform into Different Resistive Loads (Typical Values)**

| Patient's Impedance (Ohms) | Phase 1 Delivered Start Volts | Phase 1 Delivered End Volts | Phase 1 Duration (ms) | Phase 2 Delivered Start Volts | Phase 2 Delivered End Volts | Phase 2 Duration (ms) | Total Energy Delivered (J) |
|---|---|---|---|---|---|---|---|
| 25 | 1869V | 997V | 3.3ms | 997V | 287V | 3.2 ms | 305J |
| 50 | 1906V | 1220V | 4.5ms | 1220V | 643V | 3.2 ms | 270J |
| 75 | 1918V | 1306V | 5.8ms | 1306V | 846V | 3.2 ms | 246J |
| 100 | 1925V | 1351V | 7.0ms | 1351V | 971V | 3.2 ms | 229J |
| 125 | 1928V | 1378V | 8.3ms | 1378V | 1054V | 3.2 ms | 216J |
| 150 | 1931V | 1396V | 9.5ms | 1396V | 1114V | 3.2 ms | 207J |

## ENERGY LEVELS AND PATIENT IMPEDANCE

The Biphasic Truncated Exponential (BTE) waveform utilizes variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 20-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the above waveform tables. The accuracy of the energy for the energy in a 50 Ohm resistor is ±15%.

# RHYTHMX ECG ANALYSIS PERFORMANCE

The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm.

This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest.

## CARDIAC RHYTHMS USED TO TEST THE RHYTHM RECOGNITION DETECTION SYSTEM FOR CARDIAC SCIENCE AED

| Rhythm Class | Specifications |
|---|---|
| Shockable Rhythm – VF | Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity[a] of >90% |
| Shockable Rhythm – VT | Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75% |
| Non-Shockable Rhythm – NSR | Meets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity |
| Non-Shockable – Asystole | Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95% |
| Non-Shockable – all other rhythms | Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95% |

For detailed information, contact GEMS IT for white papers:

P/N 112-2013rD: Pediatric Defibrillation Instructions
P/N 110-0033-001: RHYTHMx White Paper
P/N 400781: Star Biphasic White Paper

[a] *Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682*

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# SECTION 8 – ACCESSORIES

# OVERVIEW

This section contains a list of parts and software accessories for Responder AEDs. To place an order, contact your representative or distributor.


| Topic | Page # |
|---|---|
| Responder AEDs | 55 |
| AED Accessories | 55 |
| AED Delivery Systems | 56 |
| Software Accessories | 56 |
| Education Accessories | 56 |


## RESPONDER AEDs

Responder AED with text display: biphasic waveform, IntelliSense lithium battery (Model 9142), internal memory, and 1 pair of adult defibrillation electrodes.

| WITH AED QUICK RESOURCE GUIDE KIT | WITHOUT AED QUICK RESOURCE GUIDE KIT | DESCRIPTION |
|---|---|---|
| 2019198-001 | 2019436-001 | American English |
| 2019198-002 | 2019436-002 | British English |
| 2019198-004 | 2019436-004 | Portuguese |
| 2019198-005 | 2019436-005 | Spanish |
| 2019198-008 | 2019436-008 | German |
| 2019198-010 | 2019436-010 | Italian |
| 2019198-011 | 2019436-011 | French |
| 2019198-013 | 2019436-013 | Swedish |
| 2019198-014 | 2019436-014 | Danish |
| 2019198-015 | 2019436-015 | Dutch |
| 2019198-016 | 2019436-016 | Finnish |
| 2019198-017 | 2019436-017 | Norwegian |

## AED ACCESSORIES

| PART NUMBER | DESCRIPTION |
|---|---|
| 2019199-002 | Defibrillation electrodes (adult) with two-year shelf life |
| 2019199-003 | Pediatric Defibrillation Electrodes with two-year shelf life |
| 2019437-001 | IntelliSense Lithium battery for Responder AEDs |
| 2019438-001 | AED Quick Resource Guide |
| 2019439-001 | AED Quick Resource Guide kit including: Quick Resource Guide, serial cable, and CD-ROM containing manual, RescueLink, and MDLink |
| 201616-001 | AED Quick Start Tool Kit CD-ROM |

### AED DELIVERY SYSTEMS

| | |
|---|---|
| 2019199-001 | Soft-sided carrying case for Responder AED |
| 2019615-001 | Ready Kit: includes nitrile gloves, razor, scissors, towel, 4” gauze, antiseptic wipes, one way filter mask |
| 2019199-005 | AED Wall mount storage case |
| 2019199-006 | AED Wall mount storage case with strobe light alarm |
| 2019199-004 | Wall rack |

### EDUCATION ACCESSORIES

| | |
|---|---|
| 2019199-007 | Cardiac Science AED Trainer (North American) |
| 2019613-001 | Cardiac Science AED Patient Simulator |

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# Responder AED

*automated external defibrillator*